IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

ANGELA BONANNO, Plaintiff, v. AMERICAN MEDICAL SYSTEMS, INC.; AMERICAN MEDICAL SYSTEMS, LLC, individually and f/k/a AMERICAN MEDICAL SYSTEMS, INC.; AMERICAN MEDICAL SYSTEMS HOLDINGS, INC.; ASTORA WOMEN'S HEALTH, INC.; ASTORA WOMEN'S HEALTH LLC; ASTORA WOMEN'S HEALTH HOLDINGS, LLC; ASTORA HOLDINGS, LLC, Defendants.	)	Case No. _____

PLAINTIFF'S ORIGINAL COMPLAINT

COMES NOW Plaintiff Angela Bonanno and files her Original Complaint, complaining of Defendants American Medical Systems, Inc., American Medical Systems, LLC individually and f/k/a American Medical Systems, Inc., American Medical Systems Holdings, Inc., Astora Women's Health, Inc., Astora Women's Health LLC, Astora Women's Health Holdings LLC, and Astora Holdings (collectively "Defendants") and in support respectfully shows the Court as follows:

PARTIES

1. Plaintiff Angela Bonanno is an individual and resident of Wentzville, St. Charles County, Missouri.

2. Defendant American Medical Systems, Inc. ("AMS") is a wholly owned subsidiary of defendant American Medical Systems Holdings Inc. and is a foreign corporation with its principal office in Minnesota.

3. Defendant American Medical Systems, LLC, ("AMS LLC") is a foreign corporation with its principal office in Delaware.

4. Defendant American Medical Systems Holdings Inc., ("AMS HOLDINGS") is a foreign corporation with its principal office in Minnesota.

5. Defendant Astora Women's Health, Inc., ("ASTORA") was a foreign corporation with its principal office in Minnesota.

6. Defendant Astora Women's Health LLC, ("ASTORA LLC") is a foreign corporation with its principal office in Minnesota.

7. Defendant Astora Women's Health Holdings, LLC, ("ASTORA HOLDINGS") is a foreign corporation registered in Delaware.

8. Defendant Astora Holdings, LLC, ("ASTORA HOLDINGS LLC") is a foreign corporation registered in Delaware.

9. At all times material to this action, Defendants have designed, patented, manufactured, labeled, marketed, and sold and distributed a line of pelvic mesh products. These products were designed primarily for the purposes of treating stress urinary incontinence and pelvic organ prolapse. These products share common design elements and common defects. Moreover, each of these products was cleared for sale in the U.S. after the Defendants made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety or efficacy.

VENUE

10. Defendants have significant contacts in Missouri such that they are subject to personal jurisdiction. On information and belief, Defendants are and at all relevant times were engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing in interstate commerce, either directly or indirectly through third parties or related entities, its products including the pelvic mesh products implanted into Plaintiff. At all relevant times, Defendants conducted regular and sustained business in Missouri by marketing, selling, and distributing their pelvic mesh products, including the product implanted in Plaintiff. Upon information and belief, at all times relevant, Defendants transacted, solicited, and conducted business in the State of Missouri and derived substantial revenue from such business. At all relevant times, Defendants expected or should have expected that their acts would have consequences within the United States of America, including the State of Missouri.

11. Plaintiff is seeking damages in excess of $75,000. Subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332.

12. Claims arising from the same operative facts described herein against other transvaginal mesh manufacturers were previously pending in MDL No. 2325 in the United States District Court for the Southern District of West Virginia, In Re: American Medical Systems, Inc., Pelvic Repair System Products Liability Litigation.

FACTUAL BACKGROUND

TRANSVAGINAL MESH PRODUCTS SOLD BY DEFENDANTS

13. At all times relevant herein, Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, marketing, packaging, labeling, and selling such devices, including the Monarc Sling System ("Monarc"). The Monarc is

represented by Defendants to correct and restore normal pelvic function by implantation of polypropylene mesh in the pelvis tethered in place by two arms that extend up through a woman's pelvis. The Monarc was specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma, and minimal pain while correcting urinary incontinence.

14. Prior the implantation of the Monarc at issue in this claim, Defendants sought and obtained Food and Drug Administration ("FDA") clearance to market the Monarc under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

15. Despite claims that the monofilament polypropylene mesh in the Monarc is inert, the scientific evidence shows that this material is biologically incompatible with human tissue and promotes an immune response. This immune response promotes degradation of the mesh material and can contribute to the formation of severe adverse reactions to the mesh.

16. The Monarc was marketed to the medical community and to patients as safe, effective, and reliable medical devices that can be implanted by safe, effective, and minimally invasive surgical techniques.

17. Defendants marketed and sold the Monarc through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing and the provision of valuable cash and non-cash benefits to healthcare providers. Defendants also utilized documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety, utility, and efficacy of the Monarc and its other transvaginal mesh products.

18. Contrary to the representations and marketing of Defendants, the Monarc has high failure, injury, and complication rates, fails to perform as intended, requires frequent and often debilitating revision surgeries, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff Bonanno. The defects stem from many issues, including:

a. the use of polypropylene material in the Monarc and the immune reaction that results;

b. the design of the Monarc to be inserted transvaginally into an area of the body with high levels of pathogens that adhere to the mesh, which can cause immune reactions and subsequent tissue breakdown;

c. the contraction and/or shrinkage of the mesh and surrounding scar tissue;

d. biomechanical issues with the design of the mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade and the device to migrate into organs and surrounding structures;

e. the use and design of anchors in the Monarc that when placed correctly are likely to pass through and injure major nerve routes in the pelvic region;

f. degradation of the mesh itself over time which causes the internal tissue to degrade;

g. the welding of the mesh itself during production, which creates a toxic substance that contributes to the degradation of the mesh and host tissue; and

h. the design of the trocars (devices used to insert the Monarc into the vagina) requires tissue penetration in nerve-rich environments, which results frequently in the destruction of nerve endings.

19. Upon information and belief, Defendants has consistently underreported and withheld information about the propensity of its Monarc to fail and to cause injury and complications and

has misrepresented the efficacy and safety of its transvaginal mesh products, including the Monarc, through various means and media, actively and intentionally misleading the public.

20. Despite the chronic underreporting of adverse events associated with the Monarc, enough complaints were recorded for the Food and Drug Administration ("FDA") to issue a public health notification regarding the dangers of these devices.

21. On October 20, 2008, the FDA issued a Public Health Notification that described over a thousand (1,000) complaints (otherwise known as "adverse events") that had been reported over a three-year period relating to the Monarc and other similar products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that Defendants is one of the manufacturers of the products that are the subject of the notification.

22. On July 13, 2011, the FDA issued a Safety Communication entitled, "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of pelvic organ prolapse was an area of "**continuing serious concern**." (emphasis added) The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse were "not rare." These serious complications include, but are not limited to, neuromuscular problems, vaginal scarring/shrinkage, and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization. The FDA concluded that it was not clear that transvaginal repair of pelvic organ prolapse and stress urinary incontinence with mesh kits was more effective than traditional non-mesh repair of these conditions. The FDA conducted a systematic review of the published scientific literature from 1996 to 2011 and concluded that transvaginal pelvic organ

prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non mesh repair." In the July 13, 2011 Safety Communication, the FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible." The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011 was known or knowable to Defendants and was not disclosed in any manner.

23. Defendants have further known the following:

a. that some of the predicate devices for the Monarc had high failure and complication rates, resulting in the recall of some of these predicate devices;

b. that there were and are significant differences between the Monarc and some or all of the predicate devices, rendering them unsuitable for designation as predicate devices;

c. that these significant differences render the disclosures to the FDA incomplete and misleading; and

d. that its transvaginal mesh products, including thee Monarc, were and are causing numerous patients severe injuries and complications.

24. Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with others, including Plaintiff Bonanno. As a result, Defendants actively and intentionally misled and continues to mislead the public into believing that its transvaginal mesh products, including the Monarc, and the procedures for implantation were and are safe and effective.

25. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Monarc.

26. Defendants failed to design and establish a safe, effective procedure for removal of the Monarc; thus, in the event of a failure, injury, or complications, it is impossible to easily and safely remove the Monarc or parts thereof.

27. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for repair of pelvic organ prolapse and stress urinary incontinence have existed at all times relevant to this matter.

28. The Monarc was at all times utilized and implanted in a manner foreseeable to Defendants, as they generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physicians.

29. Defendants provided incomplete, insufficient, and misleading training and information to physicians to increase the number of physicians utilizing the Monarc, and thus increase the sales of these products.

30. The Monarc implanted into Plaintiff Bonanno was in the same or substantially similar condition as when it left the possession of Defendants, as well as being in the condition directed by and expected by this Defendant.

31. Plaintiff Bonanno and her physicians foreseeably used and implanted the Monarc, and did not misuse or alter these products in an unforeseeable manner.

32. The injuries, conditions, and complications suffered by women who have been implanted with the Monarc include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, recurrent and chronic infections, and prolapse

of organs. In many cases, these women have been forced to undergo intensive medical treatment, including, but not limited to, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and surgeries to remove portions of the female genitalia, to locate and remove mesh, and to attempt to repair pelvic organs, tissue, and nerve damage.

33. The medical and scientific literature studying the effects of polypropylene pelvic mesh (like the material used in the Monarc) have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

34. Defendants knew and had reason to know that the Monarc could and would cause severe and grievous personal injury to the users/recipients of the Monarc, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

35. At all relevant times herein, Defendants continued to promote Monarc as safe and effective even when no clinical trials had been done supporting long or short term efficacy.

36. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff Bonanno and the public on notice of the dangers and adverse effects caused by implantation of the Monarc.

37. The Monarc was defective as marketed due to inadequate warnings, instructions, labeling, and/or inadequate testing.

Medical Care at Issue

38. On November 20, 2013, Plaintiff Bonanno underwent surgery during which she was implanted with the Monarc at Mercy Hospital St. Louis to treat her urinary incontinence, the use for which Defendants marketed and sold these products.

39. As a result of the implantation of the Monarc, on or about October 15, 2018, Plaintiff Bonanno underwent surgery to remove the Monarc mesh at FHMG Florida Hospital Medical Group in Altamonte Springs, FL.

40. As a result of the implantation of the Monarc, Plaintiff Bonanno suffered and will continue to suffer serious bodily injuries, including pain, recurrent urinary tract infections, discomfort, hospitalization, additional surgery(ies), continued incontinence, and the erosion of the Monarc into her surrounding organs and tissues.

CAUSES OF ACTION

COUNT I – STRICT LIABILITY FOR FAILURE TO WARN

41. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

42. At all pertinent times, Defendants were manufacturing, marketing, testing, promoting, selling and/or distributing the Monarc in the regular course of business.

43. At all pertinent times, the Monarc was implanted in Plaintiff to treat her urinary incontinence, which is a reasonably foreseeable use.

44. At all pertinent times, Defendants in this action knew or should have known that the use of the Monarc causes severe and debilitating complications in users, including Plaintiff.

45. At all pertinent times, including the time of sale and use, the Monarc, when put to the aforementioned reasonably foreseeable use, was in an unreasonably dangerous and defective condition because it failed to contain adequate and proper warnings and/or instructions regarding the severe and debilitating complication associated with the use of the Monarc. Defendants themselves failed to properly and adequately warn and instruct Plaintiff and her implanting physician as to the risks and benefits of the Monarc given Plaintiff's need for this information.

46. Had the Plaintiff received a warning that the use of the Monarc caused severe and debilitating complications, she would not have used the same. As a proximate result of Defendants' design, manufacture, marketing, sale, and distribution of the Monarc, Plaintiff has been injured catastrophically, and has been caused severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

47. The severe and debilitating complications experienced and additional surgery, and likely future surgery, required by the Plaintiff were the direct and proximate result of the unreasonably dangerous and defective condition of the Monarc at the time of sale and consumption, including its lack of warnings; Plaintiff has suffered injuries and damages including but not limited to conscious pain and suffering of Plaintiffs, medical expenses and lost wages.

48. The Defendants' product was defective because it failed to contain warnings and/or instructions, and breached express warranties and/or failed to conform to express factual representations upon which the Plaintiff and/or her implanting physician justifiably relied in electing to use the Monarc. The defect or defects made the Monarc unreasonably dangerous to those persons, such as Plaintiff, who could reasonably be expected to use and rely upon such product. As a result, the defects were a producing cause of the Plaintiff's injuries and damages.

49. The Defendants' product failed to contain, and never contained during the lifetime of sales, adequate warnings and/or instructions regarding the severe and debilitating complications experienced by women with the use of the Monarc. For the lifetime of the sales of the Monarc, the Defendants marketed, advertised, and expressly represented to the general public that it is safe for women to use their product. The Defendants continued with these marketing and advertising campaigns despite having scientific knowledge that that their products were causing severe and debilitating complications in women when used as intended

50. Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the proper candidates for use of Defendants' pelvic mesh products, and the safest and most effective methods of implantation and use of Defendants' pelvic mesh products. Defendants failed to properly package or label their products to give reasonable warnings of danger about the product to Plaintiff and her health care providers.

51. Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the dangers of Defendants' pelvic mesh products, given the Plaintiff's conditions and need for information.

52. Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers with regard to the.

53. WHEREFORE, Plaintiff demands judgment against Defendants of compensatory damages, punitive damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

COUNT II - NEGLIGENCE

54. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

55. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of their pelvic mesh products including the Monarc, and recruitment and training of physicians to implant their pelvic mesh products.

56. Defendants were negligent in marketing, designing, manufacturing, producing, supplying, inspecting, testing, selling and/or distributing the PRODUCTS in one or more of the following respects:

a. Manufacturing, producing, promoting, selling, formulating, creating, and/or designing the Monarc without properly testing it to determine adequacy and effectiveness or safety measures, if any, prior to releasing the Monarc for consumer use;

b. In failing to properly test the Monarc to determine the increased risk of severe and debilitating injuries and complications during the normal and/or intended use of the Monarc;

c. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use the Monarc;

d. In failing to remove the Monarc from the Monarc when the Defendants knew or should have known the Monarc was defective;

e. In failing to advise physicians and ultimate users, such as Plaintiff and Plaintiff's implanting physician, as to the methods for proper patient selection and methods for reducing the frequency of and number of debilitating injuries and complications caused by the Monarc;

f. Negligently failing to adequately and correctly warn the Plaintiffs, the public, the medical and healthcare profession, and the FDA of the dangers of the Product;

g. Negligently advertising and recommending the use of the Product without sufficient knowledge as to its dangerous propensities;

h. Negligently representing that the Product was safe for use for their intended purpose, when in fact it was unsafe;

i. Negligently designing the Product in a manner which was dangerous to its users;

j. Negligently producing the Product in a manner which was dangerous to its users;

k. Negligently assembling the Product in a manner which was dangerous to its users;

l. Concealing information concerning FDA warnings from the Plaintiff and her implanting physician in knowing that the Product was unsafe, dangerous, and/or non-conforming with FDA regulations; and

m. Improperly concealing and/or misrepresenting information from the Plaintiff and her implanting physician, other healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of the Product;

n. Failing to act like a reasonably prudent company under similar circumstances.

o. Under-reporting, underestimating and downplaying the serious dangers of the Monarc and their transvaginal mesh products.

Each and all of these acts and omissions, taken singularly or in combination, were a proximate cause of the injuries and damages sustained by Plaintiff.

57. At all pertinent times, the Defendants knew or should have known that the Monarc was unreasonably dangerous and defective when put to its reasonably anticipated use.

58. As a direct and proximate result of the Defendants' negligence in one or more of the aforementioned ways, Plaintiff purchased and used, as aforesaid, the Monarc products that directly and proximately caused Plaintiff to develop severe complications, including pain, recurrent urinary tract infections, discomfort, hospitalization, additional surgery(ies), continued incontinence, and the erosion of the Monarc into her surrounding organs and tissues; Plaintiff was caused to incur medical bills, lost wages, and conscious pain and suffering.

59. WHEREFORE, Plaintiff prays for judgment against the Defendants in a fair and reasonable sum in excess of $75,000.00, together with costs expended herein and such further and other relief as the Court deems just and appropriate.

COUNT III – BREACH OF EXPRESS WARRANTY

60. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

61. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold pelvic mesh products, including the Monarc.

62. At all relevant times, Defendants intended that the Monarc be used in the manner that Plaintiff in fact used it, and Defendants expressly warranted that the Monarc was safe and fit for use by consumers, that they were of merchantable quality, that their side effects were minimal and comparable to other pelvic mesh products, and that they were adequately tested and fit for their intended use.

63. At all relevant times, Defendants were aware that consumers, including Plaintiff, would use their pelvic mesh products including the Monarc; which is to say that Plaintiff was a foreseeable user of Defendants' Monarc product.

64. Plaintiff and/or her health care providers chose the Monarc product based upon Defendants' warranties and representations regarding the safety and fitness of the Monarc.

65. Plaintiff, individually and/or by and through her physician, reasonably relied upon Defendants' express warranties and guarantees that the Monarc was safe, merchantable and reasonably fit for its intended purpose.

66. Defendants' Monarc was expected to reach and did in fact reach consumers, including Plaintiff and her implanting physicians, without substantial change in the condition in which they were manufactured and sold by Defendants.

67. Defendants breached these express warranties because the Monarc implanted in Plaintiff was unreasonably dangerous and defective and not as Defendants had represented.

68. That representations made by Defendants were, in fact, false.

69. When said representations were made by Defendants, they knew those representations to be false and they willfully, wantonly and recklessly disregarded whether the representations were true.

70. At the time the aforesaid representations were made by the Defendants and, at the time the Monarc was implanted in Plaintiff's body, the Plaintiff and her implanting physician were unaware of the falsity of said representations and reasonably believed them to be true.

71. In reliance upon said representations, the Plaintiff was induced to and did use the Monarc, thereby sustaining severe and permanent personal injuries, and being at an increased risk of sustaining severe and permanent personal injuries in the future.

72. Said Defendants knew and were aware or should have been aware that the Monarc had not been sufficiently tested, was defective in nature, and or that it lacked adequate and/or sufficient warnings.

73. Defendants knew of should have known that the Monarc had a potential to, could, and would cause severe and grievous injury to the users of the Monarc, and that it was inherently dangerous in a manner that exceeded and purported, inaccurate, and/or down-played warnings.

74. Defendants' breach of their express warranties resulted in the implantation of a unreasonably dangerous and defective product in Plaintiff's body, placing Plaintiff's health and safety in jeopardy.

75. As a result of the foregoing acts and omissions, the Plaintiff was and continues to be caused to suffer severe personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, financial or economic loss, including, but not limited to, obligations for medical service and expenses, present and future lost wages and other damages.

76. WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper

COUNTY IV – BREACH OF IMPLIED WARRANTY

77. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

78. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold pelvic mesh products.

79. At all relevant times, Defendants intended that their pelvic mesh products, including the Monarc, be implanted for the purposes and in the manner that Plaintiff or Plaintiff's implanting physicians in fact used it and Defendants impliedly warranted each product to be of merchantable quality, safe and fit for such use.

80. When the Monarc was implanted into Plaintiff to treat urinary incontinence, it was being used for the ordinary purposes for which it was intended.

81. Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranty of merchantability in consenting to have the Product implanted in her.

82. Defendants knew or were reckless in not knowing that their representations were false.

83. Defendants breached these implied warranties of merchantability because the Monarc implanted in Plaintiff was neither merchantable nor suited for the intended use as warranted.

84. Defendants breach of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product in Plaintiff's body, placing her health and safety in jeopardy.

85. As a result of the foregoing acts and omissions, the Plaintiff was and continues to be caused to suffer severe personal injuries which are permanent and lasting in nature, physical pain and

mental anguish, including diminished enjoyment of life, financial or economic loss, including, but not limited to, obligations for medical services and expense, present and future lost wages and other damages.

86. WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT V – STRICT LIABILITY – DESIGN DEFECT

87. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

88. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed the Monarc as hereinabove described that were used by the Plaintiff.

89. That the Monarc was expected to and did reach the usual consumers, handlers, and person coming into contact with said Product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

90. At those times, the Monarc was not reasonably safe for its intended use and was defective as a matter of law with respect to its design.

91. At all times herein mentioned, the Monarc was in a defective condition and was not reasonably safe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

92. Defendants knew, or should have known, that at all times herein mentioned its Monarc product was in a defective condition, and was and is inherently dangerous and unsafe.

93. Defendants with this knowledge voluntarily designed its Monarc in a dangerous condition for use by the public, and in particular the Plaintiff.

94. Defendants had a duty to create a product that was unreasonably dangerous for its normal, intended use.

95. Defendants created a product unreasonably dangerous for its normal, intended use.

96. The Monarc product, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was designed defectively in that the Product left the hands of Defendant in a defective condition and was unreasonably dangerous to their intended users.

97. The Monarc product, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached its intended users, Plaintiff and her implanting physician, in the same defective and unreasonably dangerous condition in which the Monarc was manufactured.

98. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

99. The Plaintiff could not, by the exercise of reasonable care, have discovered the Monarc's defects herein mentioned and perceived its danger.

100. The Monarc product designed manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions as the Defendants knew or should have known that the Product created a high risk of unreasonable, dangerous side effects, severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages and other damages.

101. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the designing, manufacturing, marketing, promoting, distributing, and selling of a defective product.

102. As a result of the foregoing acts and omissions the Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including but not limited to, obligations for medical services and expenses, present and future lost wages and other damages.

103. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI – NEGLIGENT MISREPRESENTATION

104. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

105. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that the Monarc product had been tested and found to be reasonably safe and effective for its intended use.

106. Plaintiff, individually and/or by and through her physician, relied upon Defendants' representations in consenting to have the Product implanted in her.

107. The representations made by Defendant were, in fact, false.

108. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer severe personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, financial or economic loss, including, but not limited to, obligations for medical services and expenses, present and future lost wages and other damages.

109. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII – PUNITIVE DAMAGES

110. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

111. The Defendants have acted willfully, wantonly, with an evil motive, and recklessly in one or more of the following ways:

a. Defendants knew or should have known that their pelvic mesh products, including the Monarc, were inherently more dangerous with respect to the risks of erosion, failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the product, as well as other severe and personal injuries which are permanent and lasting in nature;

b. Defendants attempted to misrepresent and did misrepresent facts concerning the safety of their pelvic mesh products, including the Monarc;

c. Defendants' misrepresentation included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of their pelvic mesh products, including the Monarc;

d. At all times material hereto, Defendants knew and recklessly disregarded the fact that their pelvic mesh products, including the Monarc, cause debilitating and potentially lethal side effects with greater frequency than safer alternative methods products and/or procedures and/or treatment;

e. Defendants knew and recklessly disregarded the fact that their pelvic mesh products, including the Monarc, cause debilitating and potentially lethal side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise the FDA of same;

f. Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the risk of injuries caused by their pelvic mesh products.

112. As a direct and proximate result of the willful, wanton, evilly motivated and/or reckless conduct of the Defendants, the Plaintiffs have sustained damages as set forth above.

113. WHEREFORE, Plaintiff prays for a judgment for punitive damages against all Defendants in a fair and reasonable amount sufficient to punish Defendants and deter them and others from engaging in similar conduct in the future, costs expended herein, and such further and other relief as the Court deems just and appropriate.

TOLLING STATUTE OF LIMITATIONS

114. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

115. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relationship to the Monarc were not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

116. Furthermore, the running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment and conduct. Through their affirmative

misrepresentations and omissions, Defendants actively concealed from Plaintiff the true risks associated with the Monarc product.

117. As a result of Defendants' actions, Plaintiff and Plaintiff's physicians were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiff have been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

118. Furthermore, Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of the Monarc. Defendants were under a duty to disclose the true character, quality and nature of the Monarc because this was non-public information which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to Plaintiff, her medical providers and/or their health facilities.

119. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiffs and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on Defendants' representations.

PRAYER FOR RELIEF

120. WHEREFORE, Plaintiff demands judgment against Defendants, and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

a. Compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal

injuries sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law;

b. Reasonable attorneys' fees;

c. The costs of these proceedings;

d. All ascertainable economic damages;

e. Punitive damages; and

f. Such other and further relief as this Court deems just and proper.

PLAINTIFF DEMANDS A TRIAL BY JURY.

Dated: March 26, 2021

Respectfully Submitted,

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